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Living Organ Donation by Minors: An Analysis of the Regulations in EU Member States

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Running title

Living Organ Donation by Minors in the EU

Abbreviations

EU: European Union

LD: living donation

Abstract

Living organ donation (LD) is an increasingly established practice. Whereas in the U.S. and Canada LD by minors has occasionally been reported, LD by minors seems to be largely absent in the European Union. It is currently unclear whether this is the result of a different legal approach. This

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study is the first to systematically analyze the regulations of EU Member States, Norway and Iceland towards LD by minors. Relevant regulations were identified by searching government websites, translated, compared and sent for verification to national legal experts. We identified five countries where LD by minors is allowed. In two of these (Belgium and the UK) some minors may be deemed sufficiently mature to make an autonomous decision regarding LD. By contrast, in the three other countries (Luxembourg, Norway and Sweden), LD by minors is only allowed subject to parental permission and the assent (or absence of objection) of the donor. Where allowed, regulations differ significantly with regard to the substantive and procedural safeguards in place. In view of the controversial nature of the procedure, as illustrated by recent reports and surveys, we argue for a very cautious approach and greater harmonization in countries where LD by minors is allowed.

Introduction

Living donation (LD) is an increasingly established procedure to treat patients in need of a kidney or liver transplant. Although the demographic and clinical selection criteria for living donors are expanding (1), it remains uncommon for minors to be accepted as donors. In Europe, three kidney donations by adolescents have been reported for the UK between 1986 and 2005 (2) and one small bowel transplantation involving thirteen-year old identical twins has been reported for Switzerland (3). In Canada, at least two adolescents were accepted as kidney donors between 2001 and 2011 (2,4). By contrast, in the U.S. sixty minors have donated a kidney between 1987 and 2000 (5), with six additional cases reported to the UNOS database since 2000. In addition, in the U.S. eighteen minors have been accepted as living liver donors since 1988 (6).

LD by minors is only permitted when provided for by law or, in the absence of statutory provisions, when authorized by the court. A minor is defined as an individual who has not yet attained the age of legal majority under national law. For the purposes of giving consent to medical procedures, a distinction can be made between, on the one hand, emancipated and mature minors and, on the other, immature minors. Emancipated minors are treated legally like competent adults as a consequence of compelling circumstances such as marriage, pregnancy, financial independence or being a parent (7). Even in the absence of such circumstances, minors can make autonomous medical decisions in the same way as adults, whenever they are considered sufficiently mature to do so (i.e. are considered so-called mature minors). This will be the case when, in accordance with national law or legal doctrine, minors of a certain age or with an ascertained level of cognitive and emotional development have the capacity to understand the nature and consequences of the medical decision (8,9). By contrast, for a medical procedure involving an immature minor permission must be obtained from a parent or a guardian (7). However, many jurisdictions in exceptional circumstances allow immature minors to autonomously take decisions concerning specific health-related services, such as contraception and HIV and drug testing, that they would be reluctant to seek under a parental consent requirement (7,10).

In the U.S., only the state of Michigan has enacted legislation that allows LD by a mature minor. In that state, a minor fourteen years or older may donate a kidney to a close family member with prior authorization by the court (11). The mature minor doctrine, as established by case law, has not yet not been interpreted as permitting the consent of an adolescent to an intrusive non-therapeutic procedure such as LD (12). Hence, with the exception of Michigan, parental permission will always be required when LD by a minor is considered. Out of concern for a conflict of interests on the part of the parents,

courts have occasionally been petitioned to authorize such LDs. By substituting the judgment of the minor or by focusing on her best interests, courts have authorized kidney donation by minors to a sibling as a procedure of last resort subject to parental permission and donor assent (13). Rather controversially, in these cases LD was allowed because of the alleged low risks involved and the important psychological benefits that the minor donor would supposedly experience, including heightened self-esteem, an improved relationship with the recipient and the avoidance of negative feelings such as grief and loss if the recipient were to die (14,15).

By contrast, in Canada legislation allowing LD by mature minors has been adopted in several provinces. For instance, in Ontario and on Prince Edward Island, minors who have attained the age of sixteen are deemed competent to consent to LD. In Manitoba, minors from the age of sixteen may also consent to LD, if an independent physician deems them competent to do so and the intended recipient is an intimate family member (16). As in the U.S., courts have not extended the mature minor doctrine to the context of LD, although its relevance has been defended in the light of the application of the doctrine to other major procedures, such as refusal of life-saving treatment (16). For Canada, no cases where immature minors proceeded to LD with parental permission and/or court approval have been reported.

As compared to the U.S. and Canada, the legal approach towards LD by minors has not been systematically investigated for the Member States of the European Union (EU). International legal guidance is provided in the Council of Europe's *Convention on Human Rights and Biomedicine* (17,18), ratified by seventeen EU Member States. Article 20 of the *Convention* stipulates that "no organ [...] removal may be carried out on a person who does not have the capacity to consent" (17). However, the *Convention* does not specify the age at which individuals are competent to consent, leaving this decision to the ratifying States. In addition, the EU Member States that have not ratified the *Convention* are not bound by this provision.

In order to fill this gap in the literature, we aim to analyze the legal approaches of EU Member States towards LD by minors. A better understanding of the particularities of these approaches may contribute to greater harmonization of transplant regulations within the EU and may assist in identifying appropriate legal safeguards to protect the wellbeing of potential minor living donors.

Methods

We analyzed the national legislations governing LD by minors for each of the 28 Member States of the EU, as well as for Iceland and Norway, as they belong to the organ exchange organization of the Nordic countries (Scandiatransplant). By consulting the websites of their governmental agencies, we identified national transplant legislations. If relevant legislation was absent countries were excluded from the scope of our study.

From every piece of legislation, we retrieved the sections that were relevant to answer our research question and translated them into English, unless an official English version was available. Our analysis was guided by the question: Under what conditions, if any, is LD by minors allowed under

the national law? We focused on LD by immature minors, although, where relevant, LD by mature minors was also considered.

Finally, our translations and analyses were sent for verification to legal experts in each country under study. These experts were identified through formal networks of our research institutes and by consulting the academic literature. We received feedback from experts from twenty countries (respondents are included in the acknowledgements). For the other countries, our results were verified by consulting official English translations and expert analyses in the academic literature.

Results

Out of the thirty countries under study, two (Ireland and Malta) were excluded as they currently do not have legislation on LD. In all countries under study the age of majority is eighteen years. However, we found that in one of these countries (the UK) an exception exists for one region (Scotland) where majority is attained at sixteen years.

We identified five countries where LD by minors is allowed. These were Belgium, Luxembourg, Norway, Sweden and the UK. Only in Belgium and the UK, are some categories of minors deemed sufficiently mature to make an autonomous decision regarding LD. By contrast, in Luxembourg, Norway and Sweden, LD by minors is only allowed subject to parental permission and the assent (or absence of objection) of the donor. In what follows, we will analyze the national transplant legislations in more detail, and present the legal conditions under which minors can donate organs in countries where this is allowed.

LD by minors not allowed

In twenty-three countries (19-41) LD by minors is not allowed under any circumstance. In these countries, the mature minor doctrine explicitly does not apply to LD, although in several of these countries minors may be deemed sufficiently mature to consent to healthcare interventions. As LD in these twenty-three countries is never considered to be in a minor's best interests, this kind of procedure is not allowed even with parental permission.

LD allowed with minor's consent

In Belgium and the UK (except Scotland), mature minors can consent to LD. In Belgium, LD by an immature minor is not normally allowed but the transplant law stipulates that minors from the age of twelve onwards can consent to the donation of regenerative organs if the removal normally will not have serious consequences for the donor (46). Although this provision clearly prohibits kidney donation, parliamentary proceedings surprisingly suggest that minors above the age of twelve are allowed to consent to living liver donation (43). However, given the significant risks which are associated with liver donation, it is doubtful whether this interpretation is consistent with the provision that removal must have no serious consequences (44,45).

In the UK, different legislations apply to England, Wales and Northern Ireland as compared to Scotland. In Scotland, minors cannot give consent to LD (46), although, as indicated, individuals already obtain legal majority at the age of sixteen. In England, Wales and Northern Ireland, minors

can in principle provide consent under the common law doctrine of *Gillick* competence, which requires full understanding of the nature and consequences of the intervention (47), if the requirements of the *Human Tissue Act* 2004 (ss. 1 and 33) are met (48). Nevertheless, the *Human Tissue Act*'s *Code of Practice* suggests a cautionary approach, by recommending that approval should always be obtained from a court, which would determine whether LD would be in the best interests of the minor (49).

LD allowed with parental permission and minor's assent

In Luxembourg, Norway, and Sweden the mature minor doctrine does not extend to LD but LD by immature minors is allowed. In two of these countries, namely Luxembourg and Norway, LD is only allowed if, in line with the wording of the *Convention on Human Rights and Biomedicine*, the minor "has the capacity to consent to LD". Since parental permission is always also required, the "consent" of the minor should technically be considered an assent by a minor whose capacity to understand the nature and consequences of the procedure has been ascertained but who is nevertheless not allowed to autonomously take the decision to donate.

In Luxembourg, this capacity of the minor is evaluated on a case-by-case basis. Where it is found to exist, LD may proceed subject to permission from both parents. Minors and their parents must be informed by the physician about the medical, social and psychological consequences, as well as about the importance of the procurement for the recipient (50). In Norway, the relevant capacity is presumed at twelve years. Hence, minors from that age onwards are allowed to donate an organ if their parents give permission and they themselves assent (51).

In Sweden, no such capacity on the part of the minor is required for LD to be allowed. However, the procedure should be deemed compatible with the minors' best interests, parental permission should be obtained and the organ should not be removed if the minor objects in any way (52).

In the UK, if the minor is immature (i.e. not *Gillick competent*), permission for LD can be obtained from the parents (53). In such a situation the *Human Tissue Act*'s *Code of Practice* also recommends that prior court approval be obtained. However, courts have considered it doubtful that intrusive surgery, such as LD, could ever be in the best interests of an immature minor (54).

Additional requirements governing LD by minors

In the five countries that allow LD by minors strict procedural and substantive requirements are in place (table 1). In four of these countries approval of an independent competent body is required, such as an expert committee appointed by the Ministry of Health (Luxembourg), the County Governor (Norway) or the *National Board of Health and Welfare* (Sweden). In the UK, approval should be given by a panel of the *Human Tissue Authority*, which needs to verify that all legal requirements are fulfilled and, in case of a mature minor, that consent was given freely. As indicated, in the U.K. prior court authorization should preferably also be sought. Although the approval of a court or national committee is not required in Belgium, the donation must always be preceded by a deliberation from a multi-disciplinary transplant team that is not involved in the care of the recipient.

Most of these countries also impose restrictions on the donor-recipient relationship. In Luxembourg and Belgium, minors can only donate to a sibling. In Sweden, the intended recipient must be a close relative. The Norwegian transplant law does not specify the relationship between donor and recipient. However, a preparatory paper indicates that only close family members would be accepted as potential recipients, in order to avoid mental health problems for the donor (55).

Finally, the Norwegian and Swedish transplant laws require that the procedure must cause no obvious danger to the donor's health. Similarly, in Belgium the procedure must have no serious consequences for the donor (42). However, as we indicate below, it is doubtful that serious consequences for the living donor can be ruled out. Therefore, it could be argued that in these countries LD by minors would be virtually prohibited.

The Norwegian and Swedish transplant laws further require that there are "exceptional reasons" (51,52) for allowing a minor to donate organs. Guidelines issued by the Swedish National Board of Health and Welfare indicate that this may be the case when the recipient's life or health is in serious danger (56). The Swedish law further stipulates that it must be impossible to obtain a medically suitable organ from a competent person (52), indicating that minors can only be accepted if no alternatives are available.

Discussion

This is the first study to analyze the legal approaches of EU Member States towards LD by minors. Our analysis, which also included Iceland and Norway, paints a picture that reveals striking differences with the legal approach taken in the U.S. and Canada. In the great majority of the countries we have studied, LD by minors is banned completely. Moreover, in the five countries where it is allowed, there is great reluctance to allow minors to autonomously decide to donate. In fact, this would in principle only be possible in Belgium and the UK (with the exception of Scotland). However, in Belgium the additional substantive conditions seem to rule this out in practice and in the UK authoritative guidelines emphasize that approval should always be sought from a court, deciding on the basis of the minor's best interests (53). Finally, where LD by immature minors is allowed this is often legally restricted to minors who have developed sufficient cognitive and emotional skills to adequately assent to the procedure. In any case, LD by immature minors that would go against the wishes of the minor is strictly prohibited.

The fact that 23 of the countries under consideration legally prohibit LD by minors indicates its ethically controversial character. Indeed, attitudes towards LD by minors seem to have become more restrictive over time. This is illustrated by the observation that for the few EU Member States where it is allowed, no case has been reported in the last ten years. Moreover, only 7% of European transplant centers report willingness to accept kidney donor candidates below the age of eighteen and none would do so for liver donation (57). In the U.S., the number of cases performed has steadily decreased. In the same vein, the number of U.S. transplant centers that are willing to accept minors as living kidney donors declined from 18% in the middle 1990s to 2% in 2007 (58). Three major concerns are likely to have contributed to this evolution.

First, LD by minors violates the general principle that minors (certainly those who are immature) should not undergo non-therapeutic interventions that involve more than minimal risk (59). Living kidney and liver donation are associated with mortality risks of approximately 0.03% and 0.2%, respectively (60,61). In addition, there are concerns about the long-term impact of donating an organ at young age. A recent large-scale study of kidney donors concluded that their estimated lifetime risk of developing end-stage renal disease (90 per 10,000) significantly exceeded that in a matched cohort of healthy non-donors (14 per 10,000) (62). We are aware of only one study investigating the long-term medical impact of kidney donation by minors specifically, concluding that minors are not at increased risk of early mortality, impaired kidney function, hypertension or diabetes as compared to young adult donors (18-30 years). Nevertheless, time to development of such conditions after donation was similar, revealing that minor donors will be living longer with potential adverse outcomes of LD and therefore require longer follow-up (63). As the first living-donor liver transplantation was performed only in 1989, even less is known about the long-term consequences of the procedure, especially for young donors who have a greater number of years ahead of them.

Second, the assumption that minors are likely to benefit psychologically from donating an organ has received widespread criticism. Although many adult donors consider LD to be a rewarding experience (64), it remains doubtful whether minors might experience the same type of benefits, especially when their cognitive and emotional capacities are still developing (65). In addition, critics warn that LD may also adversely impact the psychosocial wellbeing of minors, even if the recipient is a close relative (65). This line of criticism was empirically confirmed in pediatric bone marrow donors, as donor siblings exhibited more symptoms of anxiety and depression, as well as a lower self-esteem as compared to non-donor sibling (66). These findings indicate that the psychological benefits for the donor are speculative and therefore are likely insufficient justification for allowing LD by minors.

A third type of concern relates to the intimate family context of LD. Critics warn that family relationships are inherently characterized by a natural imbalance of power between parents and their children, increasing the likelihood that minors succumb to parental pressure to donate (67). In addition, it can be argued that the emotional bond between young siblings may not yet be strong enough to justify LD, especially since family attachments may change over time. Moreover, as an organ can be donated only once in a lifetime, minors will not be able to make the same choice again later in life for other recipients with whom they may have a more intimate bond, such as their partner or their own children (68).

The arguments described above reveal that minors may have important vulnerabilities as compared to adult donor candidates and should therefore be subject to a higher standard of protection. Therefore, in the countries that allow LD by minors a very cautious approach seems to be appropriate. In view of the fact that regulations differ significantly with regard to the substantive and procedural safeguards in place, further legal harmonization aimed at increasing the protection of potential minor donors seems to be warranted.

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Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation.

Supporting Information

Additional Supporting Information may be found in the online version of this article.

Table S1: Unofficial translations of legislation addressing living donation (LD) by minors.

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Table 1: countries where LD by minors is allowed

	Luxembourg	Norway	UK (England/Wales)	Belgium	Sweden
Mature minors (minor can make autonomous decision to donate)	/	/	Maturity evaluated on a case-by-case basis Involvement of parents strongly recommended	Fixed age: 12 years	/
Immature minors (LD allowed with parental permission)	No lower age limit Minor must assent (Capacity evaluated on a case-by-case basis)	Fixed age: 12 years Minor must assent (Capacity presumed for minors 12 years and older)	No lower age limit Minor must not object	/	No lower age limit Minor must not object
Independent authorization	Committee of three experts appointed by the Ministry of Health, of which two physicians	County governor	HTA Panel of at least three members Court	Pluridisciplinary committee at the level of the transplant hospital	National Board of Health and Welfare
Organ type	Kidney and liver	Kidney and liver	Kidney and liver	Only regenerative organs (liver?)	Kidney and liver
Relationship with recipient	Only siblings	Not specified	Not specified	Only siblings	Only relatives
Other	/	Only in exceptional circumstances Procedure must cause no obvious danger to donor's health	/	Removal must not have serious consequences for the donor	Only in exceptional circumstances Procedure must cause no obvious danger to donor's health No suitable competent donor must be available